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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,483	07/27/2006	Toru Mizushima	KPO-LTT-P6/LTT-99/US	1765

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OSTRAGER CHONG FLAHERTY & BROITMAN PC
570 LEXINGTON AVENUE
FLOOR 17
NEW YORK, NY 10022-6894

EXAMINER	
ZAREK, PAUL E	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,483	MIZUSHIMA ET AL.	
	Examiner	Art Unit	
	Paul Zarek	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,15 and 16* is/are pending in the application.

4a) Of the above claim(s) *10 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/27/2006, 09/05/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 10 and 11 have been amended, Claims 15 and 16 have been added, and Claims 12-14 have been cancelled by the Applicant in correspondence filed on 12/31/2008. Claims 1-11, 15, and 16 are currently pending. This is the first Office Action on the merits of the claim(s).

Election/Restrictions

2. Applicant's election without traverse of Group I, drawn to a screening assay in the reply filed on 12/31/2008 is acknowledged. Claims 1-9, 15, and 16 read on the elected invention. Claims 10 and 11 are withdrawn as being drawn to a nonelected invention. That they depend on Claim, 7 and 9, respectively, is not relevant in the instant application, as they remain drawn to compounds, which are distinct and nonobvious over a screening assay.

The restriction is made FINAL.

Priority

3. Applicant's claim for the benefit of a prior-filed international application PCT/JP04/18722 (filed on 12/15/2004) under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The effective filing date of the instant application is 12/15/2004

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) to Japan application 2004-019439 (filed on 01/28/2004). The date of foreign priority of tine instant application is 01/28/2004.

Information Disclosure Statement

5. The information disclosure statement filed 07/27/2006 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. Specifically, no English equivalent or translation of Japanese patents 2003-207507, 7-171033A and 63-184063 have been provided.

Claim Rejections - 35 USC § 112 (2nd paragraph)

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-9, 15, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejected claims recite the limitation of a method of screening compounds that are "safe for gastric mucosa." It is unclear what would constitute a drug that is "safe for gastric mucosa." Acetylsalicylic acid (Aspirin), for example, can induce gastrointestinal ulcers at high doses or chronic administration. However, a single, moderate dose of acetylsalicylic acid poses no such threat. In the absence of a definition of what would constitute a compound that is "safe for gastric mucosa," the metes and bounds of the rejected claims are indefinite.

8. Claims 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 recites the limitation that "greater leakage correlates with greater gastric toxicity." Claim 16 recites the limitation that "the least leakage correlates with compounds or mixtures of compounds which are the safest for gastric mucosa." Both claims use comparative language ("greater" and "least") and relative language ("greater toxicity" and "safest") without any reference point or standard. As such, the metes and bounds of the rejected claims are indefinite.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-6, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Jorgensen, et al. (US PreGrant Publication No. 2003/0175205).

11. Claim 1 of the instant application is drawn to a screening assay comprising the following steps:

a. Preparing liposomes formed of a phospholipid and encapsulate a fluorescent dye;

b. Allow a test compound to react with the liposomes; and,

c. Evaluate the leakage of the fluorescent dye from the liposomes.

12. Claim 2 limits the phospholipid (e.g. phosphotidylcholine). Claim 3 further limits the method such that the evaluation of dye leakage (step c) is accomplished by measuring the emitted wavelength of the dye. Claims 4 and 5 limit the dye (e.g. calcein). Claim 6 further limits the method of Claim 5 such that the fluorescence of the calcein is measured at 520 nm. Claims 15 and 16 are drawn to a method similar to that of Claim 1, the only difference being that the greater the leakage correlates with greater gastric toxicity (Claim 15) or less leakage correlates to less gastric toxicity (Claim 16)

13. Claims 1, 15, and 16 provide the limitation of screening compounds that are "safe for gastric mucosa." This is not considered to be a patentably distinguishing feature of the invention as it is an intended result of the method claim, which is not considered to be a patentably distinguishing feature of the invention. "[A] whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited." *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005)(MPEP § 2111.04).

14. Jorgensen, et al., teach a screening assay in which prepared liposomes comprising phosphaditylcholine are made to encapsulate calcein (paragraph 0180). The lysis of the liposome by a test compound (e.g. snake venom PLA_2) resulted in the leakage of calcein from the liposome (paragraph 0181). The evaluation of calcein leakage was performed by exciting the calcein by light at wavelength of 492 nm, and measuring the fluorescent intensity at 520 nm (paragraph 0180 and 181). Therefore, Jorgensen, et al., anticipate all the limitations of the rejected claims.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen (above).

18. Claims 7-9 of the instant application limit the test compound to anti-inflammatory compounds (Claim 7), NSAIDs or steroids (Claim 8), or a compound that acts to protect gastric mucosa (Claim 9).

19. Jorgensen, et al., disclose a screening assay, as describe above. Jorgensen, et al., however, do not contemplate anti-inflammatory compounds or gastric mucosa-protecting compounds as the test compound. However, one of ordinary skill in the art would immediately recognize that the screening assay taught by Jorgensen, et al., can be utilized to assay any test

compound without significantly impacting the ability of the screening assay to determine which of test compounds lyse the liposomes. Any compound can be tested in the screening assay as claimed. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to utilize an anti-inflammatory compound or a compound that protects the gastric mucosa as the test compound in the screening assay.

Conclusion

20. Claims 1-9, 15, and 16 are rejected.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Rita J. Desai/
Primary Examiner, Art Unit 1625